UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/065,672	04/23/98	BILLING-MEDEL	P 6086

HM12/0426

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EXAMINER	
TURNER, S	
ART UNIT	**PAPER NUMBER**
1644	9
DATE MAILED:	
04/26/00	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/065,672	Billing-Medel
Examiner	**Group Art Unit**
Sharon L. Turner, Ph.D.	1644

☒ Responsive to communication(s) filed on *11-29-99*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-6, 11, 12, 15, and 18* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6, 11, 12, 15, and 18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit of U.S. Patent application SN 09/065,672 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Art Unit 1644.

Election/Restriction

2. Applicant's election of Group I, claims 1-6, 11-12, 15 and 18 in Paper No. 7, mailed 11-24-99 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-6, 11-12, 15 and 18 are pending. Claims 7-10, 13-14, 16 and 17 are canceled.

Double Patenting

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6, 11-12, 15 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-16, 30, 33, 35, 38 and 48 of copending Application No. 09/065,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fragment and percent identity language in instant claims renders the claimed nucleotides obvious in view of the claims of the '383 application because the nucleotide fragments with % identity of instant claims are encompassed by the claims of the '383 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 15 and 18 are rejected under 35 U.S.C. 101 because: the composition of matter comprising a gene (PS128 DNA and PS128 polynucleotides) is a product of natue and thus is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NOs: 1-5 and 12-14 which correspond to portions of cDNA or expressed sequence tags (ESTs) the compositions being either nucleic acids or amino acids encoded thereby. The disclosed sequences are said to be a portion of the PS128 gene. These isolated SEQ ID NO's meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to or encompass genes, epitopes, open reading frames, sequences from other species, mutated sequences, allelic variants, splice variants, and sequences that have a recited degree of identity (similarity, homology). None of these sequences meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID Nos:1-5 and 12-14 of the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic and amino acids. Nor can the skilled artisan envision any antigenic determinants (epitopes), the PS128 gene (including up- and down-stream regulatory regions and intron-exon boundaries of the chromosome) and sequences which constitute an open reading frame (directing full length gene expression). In regard to genes and open reading frames applicant is referred to Lewin ed., Genes IV, Oxford University Press 1990, p. 810 which teaches that a gene (cistron) is the seqment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding region (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons). Similarly, an open reading frame refers to this complex gene structure which encompasses the information necessary to direct expression of the full length protein structure from genomic DNA, i.e. including start and stop codons. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific nucleic and amino acids are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID Nos:1-5 and 12-14, but not the full breadth of claims meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

10. Claims 4-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the purified nucleotides consisting of SEQ ID Nos:1-5, expression vectors containing the purified nucleotides consisting of SEQ ID NOs:1-5 and a method of producing a polypeptide from said expression vectors containing the purified nucleotides consisting of SEQ ID Nos:1-5 which encodes the polypeptides consisting of SEQ ID NOs:12-14, does not reasonably provide enablement for the invention as recited in claims 4-6, 11-12 and 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. This rejection addresses the claims as they are directed to PS128 epitopes, open reading frames derived from PS128, expression

systems, cells transfected with and methods of producing polypeptides comprising sequences comprising genes, sequences having 50%, fragments and complements thereof. An epitope is described as an antigenic site on a complex antigenic molecule or particle (see in particular Benjamini ed., Immunology: A short course, Wiley Liss, 1991, p. 425, antigenic determinant and p. 427, epitope. Applicants specification provides no guidance as to the complex folding structure or antigenicity of any portion of PS128 nucleic acids and proteins. The skilled artisan further can not predict such structure and has no guidance from which to determine epitopes or antigenic determinants of any portion of PS128 nucleic acids and proteins since the PS128 protein is not disclosed and one of skill in the art would not expect any portion of the PS128 molecule to fold in its native conformation. As such, the skilled artisan would be forced into further experimentation to first determine the full lenght protein sequence, the native structure and subsequently its conformational antigenic epitopes.

In regard to open reading frames derived from PS128, expression systems, cells transfected with and methods of producing polypeptides comprising sequences comprising genes, sequences having 50%, fragments and complements thereof, the skilled artisan readily recognizes that the complementary or non-coding strand is unrelated to the coding strand. For example the complementary strand differs in nucleotide sequence, G+C content and melting temperature. Further, the different nucleotides of the non-coding strand encode amino acid sequences whcih share no relationship to the protein encoded by the coding strand. The specification does not teach the skilled artisan how to use a polypeptide encoded by the complementary strand. Further,

one skilled in the art recognizes that changes in nucleic acid and amino acid sequences can unpredictably affect properties such as hybridization, protein structure and function. See in particular Jenkins et al., PCR Methods and Applications, S77-82, 1994 which teaches that even a single nucleotide substitution can alter hybridization properties and further Choh et al., PNAS, 77(6):3211-14, 1980 which teach that single residue changes affect antigenic epitope structure and function of the resulting protein molecules.

Thus, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4 are directed to polynucleotides which "selectively hybridize." The metes and bounds of the polynucleotides encompassed by the claim are indefinite because hybridization is dependent upon factors including the specific sequence structure (nucleic acids involved), the G+C content, molar salt solution, and the length of the nucleic acid molecules, see in particular Jenkins et al as set forth above.

Priority

13. Applicants claim to priority under 35 USC 120 to patent application 08/838,968 is denied because applicant does not have support for 100% identity of SEQ ID Nos:1-5 and 12-14, see Figure 1. Thus the priority date awarded instant claims is the instant filing date, 4-23-98.

Claim Rejections - 35 USC § 102 or 103

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-3, 15 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by any one of the following references alone; Genbank Accession No. AA631976, 31 October 1997, and Genbank Accession No. AA578209, 11 September 1997.

All accession No.'s teach a fragment sharing a single nucleic acid in common with SEQ ID Nos:1-5. Further, Genbank Accession No. AA578209, 11 September 1997, teaches a nucleic acid sequence which is 100% identical with SEQ ID NO:2.

17. Claims 1-3, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of the following references alone; Genbank Accession No. Z39296, 27 October 1994, Genbank Accession No. R94063, 1 September 1995, Genbank Accessio No. H72049, 2 November 1995, Genbank Accessio No. H83957, 16 November 1995 and Genbank Accession No. T83743, 1 April 1995.

All accession No.'s teach a fragment sharing a single nucleic acid in common with SEQ ID Nos:1-5. Accession H83957 is 8% identical to SEQ ID NO:1, Accession H72049 is 8% identical to SEQ ID NO:2, Accession H83957 is 8% identical to SEQ ID NO:3, Accession H72049 is 8% identical to SEQ ID NO:4, and Accession H72049 is 8% identical to SEQ ID NO:5. The complementary nucleotides are anticipated by the disclosed nucleic acid sequences. Thus, the reference teachings anticipate the claimed invention.

18. Claims 1-6, 11-12, 15 and 18 directed to an invention not patentably distinct from claims 10-16, 30, 33, 35, and 38-48 of commonly assigned 09/065,383. Specifically, instant claims drawn to polynucleotide fragments and fragments with a percent identity are encompassed by claims 10-16, 30, 33, 35 and 38-48 because the subject nucleotides are shared in common. Thus, the nucleotides of instant claims are rendered obvious by the claims of the '383 application. .

Commonly assigned '383, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) Claims 1-6, 11-12, 15 and 18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/065,383 which has a common inventor and is currently commonly owned with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35

U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. Instant claims drawn to polynucleotide fragments and fragments with a percent identity are encompassed by claims 10-16, 30, 33, 35 and 38-48 because the subject nucleotides are shared in common. Thus, the nucleotides of instant claims are rendered obvious by the claims of the '383 application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

19. Claims 1-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the following references; Genbank Accession No. AA631976, 31 October 1997, and Genbank Accession No. AA578209, 11 September 1997, Genbank Accession No. Z39296, 27 October 1994, Genbank Accession No. R94063, 1 September 1995, Genbank Accessio No. H72049, 2 November 1995, Genbank Accessio No. H83957, 16 November 1995 and Genbank Accession No. T83743, 1 April 1995, as set forth above, Genbank. Accession No. N74923, 5 April 1996, Genbank Accession No. AA280704, 3 March 1997, Genbank Accession No. Z39296, 27 October 1994, and Genbank Accession No. N80180 4 April 1996 in view of Sambrook et al, Molecular Cloning, 1989, 16.1-16.16.

Genbank Accession No. AA631976, 31 October 1997, and Genbank Accession No. AA578209, 11 September 1997, Genbank Accession No. Z39296, 27 October 1994, Genbank Accession No. R94063, 1 September 1995, Genbank Accessio No. H72049, 2 November 1995, Genbank Accessio No. H83957, 16 November 1995 and Genbank Accession No. T83743, 1 April 1995, are set forth above. Genbank Accession No.T83743 teaches a nucleotide fragment which encodes an amino acid segment which shares 40% identity with SEQ ID NO:12, Genbank Accession No. R94063, 1 September 1995 teaches a nucleotide fragment which encodes an amino acid segment which shares 50% identity with SEQ ID NO:13, Genbank Accession No N74923, 5 April 1996, teaches a nucleotide fragment which encodes an amino acid segment which shares 50% identity with SEQ ID NO:13, Genbank Accession No. AA280704, 3 March 1997, teaches a nucleotide fragment which encodes an amino acid segment which shares 50% identity with SEQ ID NO:13 Genbank Accession No. Z39296, 27 October 1994, teaches a nucleotide fragment which encodes an amino acid segment which shares 50% identity with SEQ ID NO:13, Genbank Accession No. N80180 4 April 1996 teaches a nucleotide fragment which encodes an amino acid segment which shares 57% identity with SEQ ID NO:14, Genbank Accession No. AA631976, 31 October 1997, teaches a nucleotide fragment which encodes an amino acid segment which shares 100% identity with SEQ ID NO:12 and Genbank Accession No. AA578209, 11 September 1997, teaches a nucleotide fragment which encodes an amino acid segment which shares 100% identity with SEQ ID Nos:13 and 14.

The above Accession Nos do not teach placement of the sequences in an expression vector, transfection of host cells and a method of producing the polypeptide by culture.

Sambrook et al, Molecular Cloning, 1989, 16.1-16.16 teach cloning of nucleic acids into expression vectors, transfection of host cells and a method of producing a polypeptide by culture. The skilled artisan recognizes the advantages of cloning and expressing nucleic acid sequences in order to obtain large quantities of DNA for applications such as chromosomal localization, and in order to discover the amino acid structure, function, and antigenicity of amino acids produced by such nucleic acid sequences. Thus, the skilled artisan would be motivated to clone the nucleotides of the aforementioned Accession Nos in order to determine such properties and to obtain large quantities of the DNA for applications such as chromosomal localization. One of skill in the art would expect success using such procedure given the high skill in the art. Thus, for these reasons it would have been prima facie obvious for one of skill in the art to modify the procedure of Sambrook et al by inserting the DNA of the aforementioned Accession Nos to produce expression vectors, host cells and a method of producing a polypeptide using such sequences.

Status of Claims

20. No claims are allowed.

21. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.
April 21, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640